

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

JEFFREY HIGGINS, On Behalf of His Infant	§	
Daughter and of the Class Similarly Situated	§	
and ANDROMIDA A. McCALL, On Behalf	§	
of Her Infant Daughter and of the Class	§	
Behalf Similarly Situated,	§	
Plaintiffs,	§	CIVIL ACTION
v.	§	
	§	
TEXAS DEPARTMENT OF STATE	§	NO. 5:10-cv-00990
HEALTH SERVICES and DAVID L.	§	
LAKEY, M.D., in His Official Capacity as	§	
Commissioner of the Texas Department of	§	
State Health Services and in His Individual	§	
Capacity	§	
Defendants	§	

COMPLAINT

Plaintiffs complain that Defendants deceptively and unlawfully sold, traded, bartered, and distributed blood samples collected from their children at time of birth under the mandatory newborn screening program for fees, various lab equipment, and various other purposes. The blood samples were made available to private companies for undisclosed purposes and to the Armed Forces Institute of Pathology, without Plaintiffs' knowledge or consent.

STATEMENT OF CLAIM

1. Plaintiffs bring this civil action for declaratory and injunctive relief on behalf of their infant children and the class, alleging unlawful deprivation of the children's constitutional rights by Defendants under color of law and in violation of the Fourth and Fourteenth Amendments to the U.S. Constitution. The named Plaintiffs, but not the class, also seek monetary damages.

JURISDICTION AND VENUE

2. This Court has jurisdiction over Plaintiffs' federal claims, pursuant to 42 U.S.C. §1983 and 28 U.S.C. §1331.

3. This Court is the proper venue, pursuant to 28 U.S.C. §1391, because most of the events

complained of occurred within this Court's jurisdiction and one of the Plaintiffs lives within the Court's district.

PARTIES

Plaintiffs

4. Jeffrey Higgins is a resident of San Antonio, Texas, and the father of an infant born on September 26, 2007.

5. Andromida A. McCall resides in New Orleans, Louisiana, and is the mother of an infant born March 7, 2008.

Defendants

6. David L. Lakey, M.D., is sued in his official capacity as Commissioner of the Texas Department of State Health Services ("TDSHS" or, the "Department") and, together with the Department, may be served at 1100 West 49th Street, Austin, TX 78756. Plaintiffs also sue him in his individual capacity.

7. In all actions described herein and relevant times, Defendants Lakey and TDSHS were acting under color of law and were charged with, and are responsible for, upholding the Constitutions and laws of the United States and Texas.

STATEMENT OF FACTS

8. Since 2003, if not before, Defendants have knowingly, deceptively, routinely, unlawfully and without the knowledge or consent of the infants' parents, sold, traded, bartered, and distributed blood samples obtained through the state's newborn screening program to private research companies, government agencies, and other third parties. They provided blood samples gathered from babies in Texas to private companies, such as PerkinElmer and others, in exchange for a fee or various lab and testing equipment. *See, e.g.*, Exhibit 1 (Memorandum of Agreement Between TDSHS and Biomerieux, Inc.). Defendants also secretly distributed such

blood samples to the United States Armed Forces Institute of Pathology. *See, e.g.*, Exhibit 2 (Correspondence between TDSHS and Armed Forces DNA Identification Laboratory).

9. The purposes for which the private companies and government agencies used the samples are undisclosed and unrelated to the purposes for which the infants' blood was originally drawn. Defendants have distributed, sold, bartered, and traded at least 8,800 blood samples. *See* TDSHS Use of Newborn Screening Blood Spots After Completion of Newborn Screening, <http://www.-dshs.state.tx.us/lab/nbsBloodspotsUse.-shtm>. There is no compelling state justification for such secretive, deceptive, and non-consensual activity.

10. Defendants knowingly and deceptively withheld this information during settlement negotiations in *Beleno v. Texas Department of State Health Services* in this Court (No. SA-09-CA-0188-FB (U.S. Dist. Ct, West Dist. Tex., San Antonio Div.)), a lawsuit seeking to end the unlawful storage of newborn blood samples for an indefinite amount of time. Defendants were repeatedly asked during the negotiations process whether they ever distributed or sold blood samples containing deeply private medical and genetic information to other state or federal agencies or private companies. Defendants consistently denied they had ever engaged in such a practice and attributed such concerns to paranoia on the part of the parents involved in that case. They also made similar false representations to the Texas legislature, which were videotaped.

11. Defendants, without any authority and in violation of Plaintiffs' rights, have taken the liberty to profit from the state's mandatory newborn screening program in which hospitals, birthing centers, and midwives draw blood from a baby's heel so the state can test for a variety of birth defects. Babies who show detectable disorders can be treated early to prevent disabling disorders from developing.

12. Plaintiffs do not object to the state's mandated newborn screening program so long as safeguards are in place to prevent the unlawful distribution of blood samples. They object to

Defendants expropriating an infant's blood sample and any data obtained from it through research or other means, without their knowledge or consent, effectively making it Defendants' property for undisclosed non-consensual purposes, unrelated to the purposes for which the infants' blood was originally drawn, and deriving profit therefrom.

13. Given the sensitive and highly personal information contained in the blood samples, such as DNA, and the fact that such data has been indiscriminately disclosed to private companies and federal agencies, Plaintiffs are deeply and rightfully concerned about the potential misuse of that information. Plaintiffs fear the possibility of discrimination against their children and perhaps even relatives through the use of such blood samples and research activity thereon. The secretive and undisclosed nature of Defendants' activities and their distribution of such personal information in exchange for monetary or other rewards validates Plaintiffs' concerns and directly illustrates the potential misuse to which such information is subject.

14. Under Defendants' policy and practice, researchers can use the infants' samples, which consist of five blood spots on a card, for medical research, lab equipment calibration, production of for-profit pharmaceuticals, and other undisclosed matters indefinitely, without the knowledge or consent of their parents, which are unrelated to the purposes for which the infants' blood was originally drawn.

15. This practice violates the law as well as standard, mandatory medical research protocols that require researchers to first obtain informed consent from subjects and to explain to them any privacy-related issues before they are studied. For example, the appropriate standards and protocols with regard to minor children in this instance are set out in 45 CFR §§46.116, 46.408, regulations promulgated by the U.S. Department of Health and Human Services, and include providing, among other things:

- (a) A description of the research's purpose and procedure;

- (b) Disclosure of privacy implications of the research;
- (c) Whom to call if questions arise about the research;
- (d) Parental consent; and,
- (e) A statement of no reprisals for declining to participate in the research

16. At the time when Plaintiffs' children's blood samples were taken, Defendants observed no accepted professional protocols whatsoever in this regard. In direct violation of the law, Defendants never disclosed the kinds of financial interests or transactions in which they were involved or that the samples were sold. Their non-disclosure was intentionally deceptive.

17. Defendants are aware of the legal ramifications of their actions. Defendants have already settled a similar lawsuit over these practices brought by different plaintiffs in the *Beleno* case. There, this Court held that plaintiffs stated valid, factually supported claims under the Fourth and Fourteenth Amendments. *See* Order Denying Defendants' Motion to Dismiss in *Beleno v. TDSHS*, Doc. 44, at 14-16. Nevertheless, Defendants have not as of yet accounted for and destroyed all of the outstanding blood samples that they unlawfully distributed, sold, or traded.

FIRST CAUSE OF ACTION

----- FEDERAL SEARCH AND SEIZURE PROTECTIONS

18. Defendants' actions, stated above, violated the rights of Plaintiffs' children and of the class under the Fourth Amendment to the U.S. Constitution, and continue to do so.

19. Defendants, under color of law and official authority, intentionally, and with complete, deliberate, conscious and callous indifference to the constitutional rights of Plaintiffs' children and of the class, deprived them of their right to be free from unlawful search and seizure.

SECOND CAUSE OF ACTION

----- FEDERAL LIBERTY AND PRIVACY PROTECTIONS

20. Defendants' actions, stated above, violated the liberty and privacy rights of Plaintiffs'

children and of the class under the Fourteenth Amendment to the U.S. Constitution.

21. Defendants' actions, under color of law and official authority, intentionally, and with complete, deliberate, conscious, and callous indifference to the constitutional rights of Plaintiffs' children and of the class, deprived them of their fundamental liberty and privacy rights.

CLASS ACTION

22. Pursuant to Federal Rules of Civil Procedure 23(a) and (b), Plaintiffs bring this action for declaratory and injunctive relief for all other parents similarly situated whose joinder in this action is impracticable because the class is so numerous. The anticipated number of class members is in the millions since there are approximately 370,000 live births in Texas annually.

23. There are questions of law or fact common to the members of the class that predominate over questions of law or fact affecting only individual members. The questions of law or fact common to all members of the class are whether Defendants' have violated the federal constitutional rights of the class.

24. The claims of Plaintiffs are typical of the class and representative of all persons in the class who were injured by Defendants' actions, and will be so injured in the future.

25. The maintenance of this action as a class action is superior to other available methods of adjudication in promoting the convenient administration of justice. Plaintiffs do not seek damages for the class, but only equitable relief.

26. Plaintiffs and their counsel will fairly and adequately protect the interests of the other class members. Plaintiffs' counsel is capable of zealously representing class interests and is qualified to litigate this type of action, and has done so in the past, most recently in the *Beleno* case, whereby they helped secure passage of Texas HB-1672, as codified in Chapter 33 of the Texas Health and Safety Code, Plaintiffs and their counsel will adequately assert and support the

legal claims that form the basis of this action. Plaintiffs and the class will benefit equally by virtue of this action, if the Court recognizes and vindicates their federal claims.

27. This class action may be properly maintained under Federal Rule of Civil Procedure 23(b)(2) because Defendants' conduct, pursuant to their procedures, policies, and/or practices, denied Plaintiffs' children and the class members their constitutional and final declaratory and injunctive relief will settle the legality of Defendants' challenged procedures, policies, and actions for the class as a whole.

28. The class is comprised of all similarly-situated parents whose infants' blood samples or "spots" were collected by Defendants and which they will sell, trade or distribute without the knowledge or consent of the parents and for purposes unrelated to the statutorily-required purposes for which the infants' blood was originally drawn.

DECLARATORY RELIEF

29. This suit involves an actual controversy within the Court's jurisdiction, and the Court may declare the rights of Plaintiffs and the class under the Constitution and laws of the United States and vis-à-vis Texas HB-1672, as codified in Chapter 33 of the Texas Health and Safety Code, and grant such necessary and proper relief.

INJUNCTIVE RELIEF

30. Plaintiffs' claim for injunctive relief is authorized by Federal Rule of Civil Procedure 65 and by the general legal and equitable powers of this Court.

31. Because Plaintiffs and class members will continue to suffer harm due to Defendants' disregard of their fundamental rights, injunctive relief is necessary to account for the blood samples not currently in Defendants' possession which they distributed wrongfully and illegally and without the consent of the Plaintiffs and the class, and will continue to do.

32. Plaintiffs and the class will suffer irreparable harm if injunctive relief is not granted.

33. There are no adequate, measurable damages available to the class for the deprivation of their fundamental rights in this case, making injunctive relief necessary.

34. Plaintiffs and the class seek injunctive relief, commanding Defendants to halt the practices complained of herein and to account for and destroy all remaining bloodspots not in their possession and any and all information and data obtained from such bloodspots by private companies and government agencies. Such bloodspots and the data derived from them were gathered surreptitiously without informed parental consent. Plaintiffs seek that Defendants guarantee to the Court within the time period prescribed by the Court that Defendants have complied with this Court's orders.

35. Plaintiffs also ask the Court to compel Defendants to disclose for what purpose they used the blood samples and spots of Plaintiffs' children and of the class and disclose all financial transactions and all profits or benefits that accrued to Defendants.

DAMAGES

36. The named Plaintiffs, and only the named Plaintiffs, seek nominal monetary damages against Defendant Lakey in his individual capacity in the amount of \$1,000 for each blood sample taken from their infant child and wrongfully distributed to a third party.

ATTORNEYS' FEES

37. Plaintiffs are entitled to recover attorneys' fees and costs, pursuant to 42 U.S.C. § 1988.

PRAYER FOR RELIEF

Therefore, Plaintiffs respectfully pray that this Court:

A. Enter declaratory judgment for the Plaintiff individuals that:

1. Acting under authority of law, Defendants intentionally, and with complete and deliberate indifference to the rights of Plaintiffs' children, unlawfully deprived them of their right to be free from unlawful search and seizure, as guaranteed by the Fourth Amendment to the United States Constitution; and,

2. Acting under authority of law, Defendants intentionally, and with complete and deliberate indifference to the rights of Plaintiffs' children, unlawfully deprived them of their liberty and privacy interests, as guaranteed by the Fourteenth Amendment to the U.S. Constitution;
- B. Issue an injunction, commanding Defendants to forthwith account for and destroy all blood samples and spots of Plaintiffs' children, whether or not in Defendants' possession, which Defendants have distributed, sold, bartered, or traded without informed parental consent and guarantee to the Court within ten days of the order that they have done so;
 - C. Issue an injunction, commanding Defendants to advise Plaintiffs for what purposes Defendants used the blood samples and spots of Plaintiffs' children and disclose all financial transactions involved with the use of such samples and blood, within ten days of the order;
 - D. Certify this action as a class action on behalf of all similarly-situated parents whose infants' blood samples or "spots" were or will be sold, traded or distributed by Defendants for purposes unrelated to the statutorily-required purposes for which the infants' blood was originally drawn, without the knowledge or consent of the parents, and thereafter:
 1. Enter the same declaratory relief as to class, as prayed for above for the Plaintiff individuals and determine the extent to which HB-1672, as codified in Chapter 33 of the Texas Health and Safety Code and implemented by Defendants, satisfies the requirements of the Fourth and Fourteenth Amendments to the federal constitution;
 2. Issue an injunction, commanding Defendants to forthwith account for and destroy all blood samples and spots sold, traded, bartered, or distributed without informed parental consent and guarantee to the Court with ninety days of the order that they have done so;
 3. Issue an injunction, commanding Defendants to advise each class member for what purposes Defendants used the blood samples and spots of the class member and disclose all financial transactions involved with the use of such samples and blood, within ninety days of the order;
 4. Issue an injunction, commanding Defendants, their agents, successors in office, and all those acting in concert with them to cease and desist immediately from the actions complained of herein.
 - H. Order Defendant to pay Plaintiff's attorneys' fees and costs; and,
 - I. Grant all other and additional relief to which Plaintiffs may be entitled in this action, at law or in equity.

Dated: December 8, 2010

Respectfully submitted,

/s/ James C. Harrington
James C. Harrington
State Bar No. 09048500

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